

## **REMARKS**

Claims 1 – 5, 7 and 9 – 11 are pending in the present Application. Claims 1, 3, 4 and 9 have been amended, leaving Claims 1 – 5, 7 and 9 – 11 for consideration upon entry of the present Amendment. Reconsideration and allowance of the claims are respectfully requested in view of the above amendments and the following remarks.

### **Amendments to the Claims**

Claims 1, 3, 4 and 9 have been amended to replace the term “isotonic reagent” with the term “water-soluble inorganic salt”. Support for this amendment can at least be found in the specification as originally filed on page 10, lines 1-7.

### **Claim Rejections Under 35 U.S.C. § 102(e)**

Claims 1 – 3, 5, 7, 9 – 11 stand rejected under 35 U.S.C. § 102(e), as allegedly anticipated by Vukmirovic et al. (WO 2004/006958) (hereinafter “Vukmirovic”). (Office Action, 11/09/09, page 2). Applicants respectfully traverse this rejection.

In response to the Office Action dated 03/30/09, Applicants submitted a certified English translation of the Korean priority application, KR 10-2003-0037060, filed June 10, 2003, thereby perfecting Applicants priority claim to the date of June 10, 2003.

In making the present rejection, the Examiner stated that Applicant cannot rely upon the foreign priority because the invention as claimed in the instant application is not described in foreign priority document Korean application KR 10-2003-0037060. (OA 11/09/09, page 3-4)

Applicants respectfully disagree with the Examiner’s assessment. However, in order to facilitate prosecution and the allowance of the claims, Applicants have amended the claims to replace the term “isotonic reagent” with the term “water-soluble inorganic salt”.

Amended Claim 1 is now directed to an aqueous formulation of human erythropoietin, comprising: the human erythropoietin; a non-ionic surfactant; 0.001 to 0.1% (w/v) of a polyhydric alcohol; a neutral amino acid; 0.1 to 1.0% (w/v) of a sugar alcohol; a water-soluble inorganic salt; and a buffering reagent.

Applicants contend that support for each of the amended claims is found in the instant



application as well as in the priority document Korean application KR 10-2003-0037060. Specifically, support for each of the elements in amended claim 1 is detailed below.

With regard to the instant application, support can be found for the nonionic surfactant on page 6, lines 21-22. Support can be found for 0.0001 to 0.1% (w/v) of polyhydric alcohol can be found on page 8, lines 10-11, and on page 9, lines 4-5. Support for the neutral amino acid can be found on page 7, lines 20-22. Support for 0.1 to 1.0 % (w/v) sugar alcohol can be found on page 9, lines 11-14. Support for the water-soluble inorganic salt can be found on page 10, lines 1-7. Support for the buffering reagent can be found on page 10, lines 20-21.

With regard to Korean application KR 10-2003-0037060, support can be found for the nonionic surfactant on page 7, lines 19-10. Support for 0.0001 to 0.1% (w/v) of polyhydric alcohol can be found on page 9, lines 9-10 and 18. Support for the neutral amino acid can be found on page 8, lines 22-24. Support for 0.1 to 1.0 % (w/v) sugar alcohol can be found on page 10, lines 23-24. Support for the water-soluble inorganic salt can be found on page 9, line 21 to page 10, line 1.

Furthermore, support for the specific combination of each of the claimed elements is present in Example 1 as found in both the instant specification and the priority document Korean application KR 10-2003-0037060. Specifically, the aqueous formulation of Example 1, as detailed in the instant application and in Korean application KR 10-2003-0037060, comprises erythropoietin, a non-ionic surfactant (polysorbate 20), 0.001 – 0.1% of a polyhydric alcohol (propylene glycol), a neutral amino acid (glycine), 0.1- 1.0% of a sugar alcohol (mannitol), a water-soluble inorganic salt (sodium chloride) and a buffering reagent (10mM phosphate buffer). (See Example 1, on page 11 of the instant specification, and Example 1, on page 11 of Korean application KR 10-2003-0037060)

Thus as detailed above, support for the presently claimed invention is described in both the instant application and in foreign priority document Korean application KR 10-2003-0037060. Furthermore, since the claimed invention is described in the foreign priority document, Applicant's claim for priority to the date of June 10, 2003, the filing date of Korean priority application KR 10-2003-0037060, is thus perfected.

With regard to Vukmirovic, the effective priority date of WO 2004/006958 to Vukmirovic is the PCT filing date of July 14, 2003. Thus, Vukmirovic was filed after the effective priority



date of the instant application and therefore is not a proper §102(e) reference.

Applicants therefore request withdrawal of this rejection and an allowance of the claims.

Claim Objections

Claim 4 is objected to because it depends from a rejected claim. Applicants once again thank the Examiner for the lack of rejection of Claim 4, and the presumptive allowance of the claim.

It is believed that the foregoing amendments and remarks fully comply with the Office Action and that the claims herein should now be allowable to Applicants. Accordingly, reconsideration and withdrawal of the objection(s) and rejection(s) and allowance of the case are respectfully requested.

If there are any additional charges with respect to this Amendment or otherwise, please charge them to Deposit Account No. 06-1130.

Respectfully submitted,

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